Arkansas Department of Health

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Governor Asa Hutchinson
José R. Romero, MD, Secretary of Health

Aug 11, 2021

Re: Emergency Use Authorization (EUA) for the use of monoclonal antibody therapies for Post Exposure Prophylaxis of coronavirus disease 2019 (COVID-19)

Dear Colleagues,

We are writing to you to provide some recent important updates in the emergency use authorization (EUA) issued by the Food and Drug Administration (FDA) regarding monoclonal antibody therapies for COVID 19. The FDA revised the emergency use authorization (EUA) for REGEN-COV (casirivimab and imdevimab, administered together) on 7/30/2021 authorizing REGEN-COV for emergency use as post-exposure prophylaxis (prevention) for COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. **REGEN-COV is not authorized for pre-exposure prophylaxis to prevent COVID-19 before being exposed to the SARS-CoV-2 virus -- only after exposure to the virus.**

Prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19.

REGEN-COV should only be used as post-exposure prophylaxis for individuals who are:

- not fully vaccinated **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, people with immunocompromising conditions, including those taking immunosuppressive medications[1]), **and**
    - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC), **or**
    - who are at high risk of having been exposed to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

REGEN-COV also remains authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

These monoclonal therapies have been shown to be highly effective when given early in disease course in preventing hospitalizations and emergency room visits in high-risk patients. In light of recent rapid increases in COVID-19 hospitalizations in Arkansas, using monoclonal antibody therapy to prevent patients from being hospitalized is critical at this time. Recent updates expand the definition of "high-risk" patients who are eligible for treatment and provide greater latitude to healthcare providers to exercise their clinical judgment. Clinicians may now refer any adult or pediatric (age 12 years and older

and ≥40 kg) patient if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19, including:

- Older age (aged ≥65 years)
- Obesity (BMI >25)
- Diabetes
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (e.g., chronic obstructive pulmonary disease, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension)
- An immunocompromising condition or immunosuppressive treatment (based on theoretic considerations, many experts strongly recommend therapy for patients who are immunosuppressed despite their limited representation in clinical trials).
- Chronic kidney disease
- Pregnancy
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above. See the EUA for more details.

Currently, there are 2 monoclonal antibody products available for treatment of COVID 19: REGEN-COV (distributed through US Health and Human Services [HHS]/Office of the Assistant Secretary for Preparedness and Response {ASPR]) and Sotrovimab. Distribution of bamlanivimab/etesevimab has been paused by ASPR on a national basis until further notice. In addition, FDA recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies and not use bamlanivimab and etesevimab administered together at this time. Lab studies indicate that both REGEN-COV and Sotrovimab retain efficacy against the delta variant, which is the main driver of the current rise in cases in Arkansas. Additional changes in the EUA for REGEN-COV allow for administration by intravenous infusion or subcutaneous injection.

At this time, we encourage all of you to discuss the option of monoclonal antibody therapy with patients in your practices. Subcutaneous injections can be utilized for delivery of REGEN-COV. REGEN-COV can be ordered free of charge. If you need assistance or guidance in setting up an account with Amerisource-Bergen please contact Elizabeth Woodland at Elizabeth.woodland@arkansas.gov.

Monoclonal antibody therapy may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

Other informational resources including locations where monoclonal antibody therapies are available through Arkansas and updates can be found on https://www.healthy.arkansas.gov/programs-services/topics/covid-19-guidance-about-monoclonal-antibodies

1. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html